REMARKS

Applicant submits that the present amendment is fully responsive to the Office Action dated June 16, 2010 and, thus, the application is in condition for allowance.

By this reply, claims 50, 53, 59 and 62 are amended. Claims 50, 53, 56, 57, 59-62 and 65-75 remain pending. Of the pending claims, claims 50, 53, 59 and 62 are independent. An expedited review and allowance of the application is respectfully requested.

At the onset, Applicant's representative extends his sincere gratitude to Examiner of record Ou and Primary Examiner Julian Woo for graciously agreeing to an interview at the USPTO on August 26, 2010 with Applicant's representative, inventor Dr. David Diduch, and device expert, Mr. David Gregoire. During such interview, Applicant's representative presented a description of the invention, particularly pointing out some of the many advantages of the exemplary embodiments of the present invention. An exemplary device within the scope of the present claims was shown. Then the cited art of record was discussed, and how the present invention is distinguishable over the cited art of record. For example, none of the cited art of record, alone or in combination, disclose or fairly suggest a device which includes an elongate member which is in a substantially straight stressed configuration substantially contained within the lumen of the cylindrical body and a substantially curved unstressed configuration when extended distally through the lumen to outside of the jaws. Further, none of the art of record teaches a device having suture which is substantially outside of the outer tubular member of the body. Further, each of the references used were so divergent in their architecture and function that any substitution of any components of one within the other would render an unfunctionable "combination" device. Applicant's unique geometry and design have advantages that were not appreciated or inherent within the devices of the references cited, which either show a straight

needle configuration and associated device with suture being directed into a lumen of the device, or a curved needle and associated device, or devices which are used just for suture welding. These references are not combinable in any manner as the straight needle device simply cannot operate with a curved needle and the curved needle device simply cannot operate with a straight needle. The welding device is inapplicable to the other two devices. The present amendment reflects the clear distinctions between the art of record and the present invention, which present claims the examiners deemed would overcome the references of record. Thus, an allowance of the claims is respectfully requested.

In the outstanding Office Action, claims 50, 53, 56, 57, 59-62 and 65-67 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Thal (U.S. Publ. App. No. 2002/0103493) in view of Middleman (U.S. Pat. No. 5,749,879) in view of Mollenauer (U.S. Pat No. 6,077,277). It is asserted that Thal discloses substantially the same invention as recited in the pending claims but for "an elongated member positioned substantially within and slideable through the lumen of the body for carrying a suture, wherein the distal portion comprises a flexible, closed-loop eyelet." It is further asserted that Middleman and Mollenauer do teach these deficiencies and thus it is concluded that the combination of these three references would render the present claims as obvious. Applicant respectfully traverses.

Neither Thal, nor Middleman, nor Mollenauer, nor any other reference of record, alone or in combination, can teach or fairly suggest the present invention as recited in the pending claims. In general, each of the references allegedly disclose some claimed element(s) of the pending claims, and yet, more importantly, each reference teaches a unique device with particular components, features and attributes that only work in the particular manner described for that particular device in that particular reference. Stated differently, each referenced device is

uniquely designed in the manner taught in the reference and any change or modifications to such device would completely defeat the very design or purpose of that referenced device. Thus, any alleged "combination" of such referenced devices, particularly in the manner alleged in the Office Action, would not only teach against the very unique attributes of that referenced device, but would also result in a combined device which is wholly inoperable.

More particularly, Thal fails to disclose or fairly suggest the present invention as recited in the pending claims because, in sharp contrast to the assertion in the Office Action, Thal fails to disclose, among other things, a cylindrical body having a lumen that can accommodate a sliding elongate member which is in a substantially straight stressed configuration substantially contained within the lumen of the cylindrical body and between the first jaw and the second jaw and a second position wherein the distal portion of the elongate member is in a substantially curved unstressed configuration and extends through and beyond the opening in the first jaw. These cited features are not only completely absent in Thal, but Thal even teaches a nearly opposite mechanism, a retrieving mechanism, as opposed to a suture passing mechanism according to the present invention. As shown in Figs. 2A-2C, Thal teaches a naturally straight unstressed needle carrying a suture directed in from an external device position, and then inserted into the jaw (as opposed to an area between the jaws), from where the needle is then advanced through the curved configuration of the jaw until it is extracted completely through an opening 24 from the opposite end of the device. Thus, Thal must be used with an external, straight needle because any type of curved needle would not only not make sense to use with such mechanism, but would make it nearly impossible to insert into the lower jaw through the upper jaw of Thal. Thus, Thal is clearly designed for straight needle use and use of any type of curved needle would teach against the mechanism and device disclosed.

Middleman cannot cure the deficiencies of Thal because Middleman also does not teach or suggest the features as recited in the claims. Middleman, at best, only shows a flexible needle with no jaw or grasping mechanism whatsoever. All of the Middleman techniques are designed to go around structures and pull them in rather than pierce through them. In contrast, the Thal reference discloses pure piercing with a needle. Thal must use a piercing needle and Middleman uses a non-piercing and flexible needle with no transverse opening whatsoever for retaining suture, and further must surround its target tissue to operate. These are wholly different mechanisms and the substitution of one within the other would simply make the other not work.

Any type of substitution of the Middleman needle into the Thal mechanism would result in a completely useless device. As disclosed in Thal, a separate and externally maintained needle is inserted into the jaw and then pushed through the internal passage until it is extracted from an opening 24 on the other side of the device. Just attempting to insert the naturally curved needle of Middleman into the jaw opening of Thal would be an exercise in futility because the naturally curved tip of Middleman is not designed at all for insertion into tissue, let alone specifically designed jaw openings designed to intake sharp edged, straight needles (as disclosed in Thal). Further, the naturally curved Middleman needle would be difficult to insert into the jaw opening in the Thal device which is designed to accommodate a straight needle. Finally, even if one were able to miraculously insert the Middleman needle into the Thal jaw opening, the resultant device would be wholly inoperable because no suture could be pulled through the Thal device. The curved tip of the Middleman needle is purposely curved back because its intended use and design is to hook onto and pull suture backwards rather than to grasp suture and push it forward. Thus, it would simply be impossible to push suture through the Thal device using the Middleman needle. Hence, the combination of these two references is inoperable.

Finally, Mollenauer cannot not cure the deficiencies of Thal and Middleman because it, too, is designed for only its intended purpose and any modification of the device whatsoever would result in its inoperability. Mollenauer is a suture welding device, used for melting sutures after stitches are made. It necessarily uses jaws with heating surfaces which when pressed together, aid in melting the suture. The Mollenauer device would be completely inoperable if it had jaws with openings in them to allow a curved needle and suture therethrough. Mollenauer only works if the suture is capable of being completely maintained within the heated-surface teeth of its jaws for the length of the jaw. Any attempt at providing a hole in any of the jaws for accommodating a curved needle would completely steer away from the very purpose of the welding mechanism. Further, any type of curvature in the needle carrying the suture in Mollenauer would completely make the device inoperable as well as the Mollenauer jaws absolutely require that the needle and suture are maintained relatively straight through the teeth of the jaws. So it is wholly inconceivable how Mollenauer would work in any way with a naturally curved needle such as that used in Middleman. Further, substituting a closed loop eyelet, as allegedly disclosed by Mollenauer, for the hook mechanism taught in the Middleman needle tip would defeat the purpose and function of the Middleman device which is to hook onto and pull suture back. A closed-loop eyelet, as disclosed by Mollenauer, would simply not operate in the Middleman device and would teach against the Middleman reference.

Thus, although each reference is being used to allegedly disclose some element(s) of the present invention as recited in the pending claims, each reference has glaring functional and feature deficiencies. There is no motivation to combine these three very different references. Even if there were some motivation to combine them, *arguendo*, the combination would not be able to render the present claims as obvious because the combination would simply not work. It

is inconceivable how Thal, which absolutely relies on the criticality of a straight needle, would work with a superelastic (Middleman) or flexible (Mollenauer) needle. The mechanism in the jaw (see Thal, Fig. 1) is especially designed to house and guide a straight needle therethrough. The Thal needles are specifically designed to be straight and cannot in any non-futile way be conceived to be anything other than straight. Thus, any use or intention of a curved needle would destroy the very function of Thal. Thus, Thal is simply not combinable with any other reference that teaches a curved needle or path, such as Middleman. Middleman does not teach, among other things, the use of jaws or the notion of a piercing needle. As shown in the Fig. 1-7 series of Middleman, it is inconceivable how any jaws would be used in the Middleman device because such jaws, even if they would be added, would be wholly inoperable or nonfunctional as the flexible needle in Middleman is designed to extract from its holding cylinder then curve around and bring in a suture based on its pre-formed shape. A jaw in Middleman would interfere with this intended use. Finally, Mollenauer simply cannot function with any type of jaw that has an opening intended to push needle and suture therethough, let alone a naturally curved needle, which would make the welding of the suture nearly impossible. Thus, each of the references, besides not disclosing the features and elements recited in the pending claims, teaches a mechanism that is specific to that device and any change or alteration or combination with any of the other references would render the reference as wholly inoperable. For at least these reasons, the references cannot be combined in a functional matter to render the present claims as obvious. Thus, for at least the reasons set forth above, all pending claims should be allowed and the application allowed to proceed to issue.

No extension of time is believed necessary to enter this amendment. If any fees are associated with the entering and consideration of this request for consideration, please charge such fees to our Deposit Account 50-2882.

As all of the outstanding rejections have been traversed and all of the claims are believed to be in condition for allowance, Applicant respectfully requests issuance of a Notice of Allowance. If the undersigned attorney can assist in any matters regarding examination of this application, Examiner is encouraged to call at the number listed below.

Respectfully submitted,

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